



*ITW*

Practitioner's Docket No. U 014681-4

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application  
of \_\_\_\_\_  
Inventor(s)

for \_\_\_\_\_  
Title of invention

**OR**

In re application of: Prasad K. **DESHPANDE**, et al  
Serial No.: 10/749,932                      Group No.: 1614  
Filed: December 31, 2003                      Examiner: N/A  
For: BENZOQUINOLIZINE-2-CARBOXYLIC ACID ARGININE SALT TETRAHYDRATE

**Commissioner for Patents**  
**P. O. Box 1450**  
**Alexandria, VA 22313-1450**

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. 1.97(b))**

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***  
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**37 C.F.R. 1.8(a)**

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Date: December 17, 2004

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Signature  
**Janet L. Cord**  
(type or print name of person certifying)

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

NOTE: 37 C.F.R. 1.98(b):

- (1) *Each U.S. patent listed in an information disclosure statement must be identified by inventor, patent number, and issue date.*
- (2) *Each U.S. patent application published listed in an information disclosure statement shall be identified by applicant, patent application publication number, and publication date.*
- (3) *Each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date.*
- (4) *Each foreign patent or published foreign patent application listed in an information disclosure statement must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application.*
- (5) *Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.*

**WARNING:** *No extension of time can be had under 37 C.F.R. § 1.36 (a) or (b) for filing an IDS. 37 C.F.R. § 1.97(f).*

NOTE: *The "filing date of a national application" under 37 C.F.R. 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 C.F.R. 1.97(b)(2).*

### **IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. 1.97(b).

NOTE: *"No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."*


NOTE: *"An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

NOTE: *"The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

**NOTE:** "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

If a fee is required, please charge deposit account 12-0425.



SIGNATURE OF PRACTITIONER

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**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Prasad K. DESHPANDE, et al.

Serial No.: 10/749,932

Group No. 1614

Filed: December 31, 2003

Examiner: N/A

For: BENZOQUINOLIZINE-2-CARBOXYLIC ACID ARGININE SALT  
TETRAHYDRATE

Attorney Docket No.: U 014681-4

**Commissioner for Patents**

**P. O. Box 1450**

**Alexandria, VA 22313-1450**

**INFORMATION DISCLOSURE STATEMENT**

We draw the attention of the Examiner to the attached references which are also listed on the attached Form PTO-1449.

Respectfully submitted,

JANET I. CORD  
LADAS & PARRY LLP  
26 WEST 61<sup>ST</sup> STREET  
NEW YORK, NEW YORK 10023  
REG. NO. 33,778 (212) 708-1935

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- ☐ transmitted by facsimile to the Patent and Trademark Office, to (703) 872-9306

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"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

FORM PTO-1449

U. S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.

SERIAL NO.

U 014681-4

10/749,932

APPLICANT

Prasad K. Deshpande, et al.

FILING DATE

GROUP

12/31/2003

1614

## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA	4,563,459	01/1986	Groher et al.	
	AB	3,845,770	11/1974	Theeuwes et al.	
	AC	3,916,899	11/1975	Theeuwes et al.	
	AD	3,536,809	10/1970	Applezweig	
	AE	3,598,123	08/1971	Zaffaroni	
	AF	4,008,719	02/1977	Theeuwes et al.	
	AG	6,514,986	02/2003	de Souza et al.	
	AH	6,136,806	10/2000	Hittel	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AJ	9414794	07/1994	WO		X
	AK	6-145167	05/1994	JP		X
	AL	9415938	07/1994	WO		
	AM	98/58923	12/1998	WO		X

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

	AO	Asahina, Y. et al. "Recent advances in structure activity relationships in new quinolones", <i>Prog. Drug Res.</i> (1992), 38: 57-106
	AP	Japanese patent application 6-145167, dated May 24, 1994
	AQ	Cooper, C.S. et al. "Preparation and in Vitro and in Vivo Evaluation of Quinolones with Selective Activity against Gram Positive Organisms", <i>J. Med. Chem.</i> 1392-1398
	AR	English abstract of WO 98/58923, dated December 30, 1998
	AS	English abstract of WO 94/14794, dated July 7, 1994
	AT	Chemical Abstracts 136:147733

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1614

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

AA	Chemical Abstracts 134:141378
AB	Chemical Abstracts 134:141377
AC	Chemical Abstracts 135: 300896
AD	Chemical Abstracts 130: 322834
AE	Chemical Abstracts 129:339430
AF	Chemical Abstracts 129:310840
AG	Chemical Abstracts 129:245024
AH	Chemical Abstracts 129: 239390
AI	Chemical Abstracts 127: 358825
AJ	Chemical Abstracts 123: 164953
AK	Chemical Abstracts 124: 86783
AL	Chemical Abstracts 124: 170377
AM	Chemical Abstracts 124:343084
AN	Chemical Abstracts 127: 302924
AO	Chemical Abstracts 131: 153420
AP	Chemical Abstracts: 136:2738

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	U 104681-4	10/749,932
	APPLICANT	
	Prasad K. Deshpande, et al.	
	FILING DATE	GROUP
	12/31/2003	1614

REFERENCE DESIGNATION			U.S. PATENT DOCUMENTS		
EXAMINER - INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA	6,329,391	12/2001	Ledoussal et al.	
	AB	4,382,892	05/1983	Hayakawa et al.	
	AC	5,859,026	01/1999	Ito et al.	
	AD	5,889,009	05/1999	Miyake et al.	
	AE	6,121,285	09/2000	Takemura et al.	
	AF	6,184,388	02/2001	Takemura et al.	
	AG	3,984,403	10/1976	Fujisawa et al.	

FOREIGN PATENT DOCUMENTS					
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION
					YES NO
	AH	0394553	06/1995	EP	X
	AI	0572259	12/1993	EP	
	AJ	0287951	10/1988	EP	

OTHER ART		(Including Author, Title, Date, Pertinent Dates, Etc.)
	AK	European Patent Specification 0394553 B1, dated June 21, 1995
	AL	Alsina J. et al. "Active Carbonate Resins for Solid-Phase Synthesis Through the Anchoring of a Hydroxyl Function. Synthesis of Cyclic and Alcohol Peptides", <i>Tetrahedron Letters</i> , (1997), 38(5): 883-886
	AM	Edwards W.B. et al. "Generally Applicable, Convenient Solid-Phase Synthesis and Receptor Affinities of Octreotide Analogs", <i>J. Med. Chem.</i> , (1994), 37(22): 3749-3757
	AN	Dhople, A.M. and M.A. Tbanez. " <i>In vivo</i> susceptibility of mycobacterium leprae to ofloxacin either singly or in combination with Rifampicin and Rifabutin", <i>Arzneimittel-Forschung</i> , (1994), 44(4): 563-565
	AO	Haustein U.F. et al. "Topical quinolone nadifloxacin (OPC-7251) in bacterial skin disease: clinical evaluation in a multicenter open trial and in vitro antimicrobiological susceptibility testing", <i>J. Dermatological Treatment</i> , (1997), 8: 87-92
	AP	Hashimoto, Koji et al. "A Practical Synthesis of (S)-(-)-Nadifloxacin: Novel Acid-Catalyzed Racemization of Tetrahydroquinaldine Derivative", <i>Chem. Pharm. Bull.</i> , (1996), 44(4): 642-645
	AQ	Irish, D. et al. "Control of an outbreak of an epidemic methicillin-resistant <i>Staphylococcus aureus</i> also resistant to mupirocin", <i>J. Hospital Infection</i> , (1996), 39: 19-26

EXAMINER	DATE CONSIDERED
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1614

## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA	4,642,355	02/1987	Nakamura et al.	
	AB	4,051,247	09/1977	Schuppan et al.	
	AC	3,924,042	12/1975	Gerster et al.	
	AD	3,985,882	10/1976	Gerster et al.	
	AE	4,399,134	08/1983	Ishikawa et al.	
	AF	4,404,207	09/1983	Stern et al.	
	AG	4,416,884	11/1983	Ishikawa et al.	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AH	0304087	02/1989	EP		
	AI	0241206	10/1987	EP		
	AJ	9914214	03/1999	WO		

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

	AK	Kido, M. et al. "Crystal Structures of Nadifloxacin Anhydride and its Hemihydrate", <i>Chem. Pharm. Bull.</i> , (1994), 42(4):872-876
	AL	Takahashi et al. "Reduction of in vitro Clastogenicity Induced by the Mixture of Optical Isomers of Nadifloxacin during Storage", <i>Arzneim.-Forsch./Drug Res.</i> , (1995), 45(1): 195-197
	AM	Sloan et al. "Definition and attainment of high purity of organic compounds", Chapter 2, 179-182, <i>Physics and Chemistry of the Organic Solid State</i> , eds. D. Fox, Labes and Weissberer. Interscience Publishers, London. 1963
	AN	Morita, S. et al. "An efficient synthesis of a key determinate towards (S)-(-)-Nadifloxacin", <i>Tetrahedron: Asymmetry</i> , (1995), 6(1): 245-254
	AO	Morita, S. et al. "Synthesis and Antibacterial Activity of the Metabolites of 9-Fluoro-6,7-dihydro-8-(4-hydroxy-1-piperidyl)-5-methyl-1-oxo-1 <i>H</i> ,5 <i>H</i> -benzo[ <i>i,j</i> ]quinolizine-2-carboxylic acid (OPC-7251)", <i>Chem. Pharm. Bull.</i> , (1990), 38(7): 2027-2029
	AP	Ishikawa, H. et al. "Studies on Antibacterial agents. I. Synthesis of Substituted 6,7-Dihydro-1-oxo-1 <i>H</i> ,5 <i>H</i> -benzo[ <i>i,j</i> ]quinolizine-2-carboxylic acids", <i>Chem. Pharm. Bull.</i> , (1989), 37(8): 2103-2108
	AQ	English translation of Yamada, Hirao et al. "Evaluation of the <i>in vitro</i> drug efficacy of Nadifloxacin Cream", <i>Iyakuin Kenkyu</i> , (2000), 31(8): 519-524

EXAMINER

DATE CONSIDERED

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## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA	4,443,447	04/1984	Gerster et al.	
	AB	4,472,406	09/1984	Gerster et al.	
	AC	4,472,407	09/1984	Stern et al.	
	AD	4,535,161	08/1985	Hayakawa et al.	
	AE	4,552,879	11/1985	Ishikawa et al.	
	AF	4,594,347	06/1986	Ishikawa et al.	
	AG	4,599,418	07/1986	Irikura et al.	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AH	02131483	05/1990	JP		
	AI	02188589	07/1990	JP		
	AJ	0018404	04/2000	WO		

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

	AK	English abstract of Japanese patent 02131483, dated May 21, 1990
	AL	English abstract of Japanese patent 02188589, dated July 24, 1990
	AM	English translation of Yamada, Hiroaki, et al. "Bioequivalency of 1% Nadifloxacin lotion and 1% of Nadifloxacin cream", <i>Iyaku hin Kenkyu</i> , (2000), 31(8): 525-528
	AN	Berge, Stephen M. et al. "Pharmaceutical Salts", <i>J. Pharmaceutical Sciences</i> , (1977), 66(1): 1-19
	AO	Abstract of Koike, M. et al. <i>Iyaku hin Kenkyu</i> , (1990), 21(5): 998-1021
	AP	Abstract of Koike, M. et al. <i>Iyaku hin Kenkyu</i> , (1990), 21(5): 1022-1033
	AQ	Abstract of Fujita, S. et al. <i>Iyaku hin Kenkyu</i> , (1990), 21(6): 1156-1176

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	AA	5,185,337	02/1993	Fujii et al.	
	AB	6,034,100	03/2000	Adachi et al.	
	AC	4,935,420	06/1990	Ueda et al.	
	AD	5,639,886	06/1997	Zerbes et al.	
	AE	5,869,661	02/1999	Ochi et al.	
	AF	4,638,067	01/1987	Culbertson et al.	
	AG	4,665,079	05/1987	Culbertson et al.	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AH	0185095	11/2001	WO		
	AI	0908181	04/1999	EP		
	AJ	9420105	09/1994	WO		

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

	AK	Abstract of Koike, M. et al. <i>Yakubutsu Dotai</i> , (1990), 5(2): 199-208
	AL	Abstract of Yasuo, A. et al. <i>Yakuri to Chiryō</i> , (1990), 18(4): 1717-1730
	AM	Abstract of Hayakawa, R. et al. <i>Hifu</i> , (1990), 32(2): 217-230
	AN	Abstract of Asada, Y. et al. <i>Yakuri to Chiryō</i> , (1990), 18(4): 1717-1730
	AO	Abstract of Awogi, T. et al. <i>Iyaku hin Kenkyu</i> , (1990), 21(4): 626-635
	AP	Abstract of Matsuzawa, A. et al. <i>Iyaku hin Kenkyu</i> , (1990), 21(4): 636-646
	AQ	Abstract of Nagao, T. et al. <i>Iyaku hin Kenkyu</i> , (1990), 21(4): 647-662

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	AA	4,822,801	04/1989	Domagala et al.	
	AB	5,097,032	03/1992	Domagala et al.	
	AC	5,051,509	09/1991	Nagano et al.	
	AD	5,607,942	03/1997	Petersen et al.	
	AE	5,677,316	10/1997	Ao et al.	
	AF	4,777,175	10/1988	Culbertson et al.	
	AG	4,874,764	10/1989	Ueda et al.	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AH	9744034	11/1997	WO		X
	AI	05339238	12/1993	JP		
	AJ	58090511	05/1983	JP		

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

	AK	English abstract of WO 97/44034, dated November 27, 1997
	AL	English abstract of JP 5339238, dated December 21, 1993
	AM	English abstract of JP 58090511, dated May 30, 1983
	AN	Abstract of Matsuzawa, A. et al. <i>Iyakuhin Kenkyu</i> , (1990), 21(4): 663-670
	AO	Abstract of Hashimoto, K. et al. <i>Iyakuhin Kenkyu</i> , (1990), 21(4): 671-677
	AP	Abstract of Furukawa, M. et al. <i>Iyakuhin Kenkyu</i> , (1990), 21(5): 989-997
	AQ	Abstract of Yoshimura, S. et al. <i>Iyakuhin Kenkyu</i> , (1990), 21(5): 1034-1052

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					YES	NO
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	AE	4,935,420	06/1990	Ueda et al.	
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	AL	Abstract of Bojar, R.A. et al. <i>Journal of Investigative Dermatology</i> , (1994), 103(3): 405
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